UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/847,809 | 05/01/2001 | Olga Bandman | PF-0358-2 DIV | 7331 |

27904 7590 10/07/2002

INCYTE GENOMICS, INC.
3160 PORTER DRIVE
PALO ALTO, CA 94304

| EXAMINER |
|---|
| CARLSON, KAREN C |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | 6 |

DATE MAILED: 10/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/847,809 | Applicant(s) BANDMAN ET AL. | |
|---|---|---|---|
| | Examin r Karen Cochrane Carlson, Ph.D. | Art Unit 1653 | |

*-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

This Office Action is a directed to a Restriction Requirement. The Claims encompass sequences drawn to two different reticular proteins RCNγ and RCNδ. These proteins are related because they are considered to be endoplasmic reticulum luminal protein and isoforms of each other (see page 3 of the specification, for example). However, the structure and function of the proteins are wholly different and therefore the nucleic acid, proteins and methods of use centering on RCNγ and RCNδ are patentably distinct. Therefore, the restriction requirement is being presented in a two-fold fashion. A first restriction is for claims and sequences related to RCNγ. A second restriction is for claims and sequences related to RCNδ.

Applicants should elect a **single** invention only, whether the invention be from any one of the two sets of restrictions set forth below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

**RCNγ**

I. Claims 1, 2, 16, 17, and 45, drawn to RCNγ having SEQ ID NO: 1, classified in class 530, subclass 350.

II. Claims 3, 4, 5, 6, 7, 9, 11, and 12, drawn to polynucleotide encoding RCNγ having SEQ ID NO: 1, classified in class 536, subclass 23.1.

III. Claim 8, drawn to transgenic organism comprising polynucleotide encoding RCNγ having SEQ ID NO: 1, classified in class 800, subclass 8.

IV. Claims 10, 30, 31, 33, 36, 37, 39-42, drawn to antibody against RCNγ having SEQ ID NO: 1, classified in class 530, subclass 387.1.

V. Claims 13 and 14, drawn to a method for detecting polynucleotide encoding RCNγ having SEQ ID NO: 1 via Southern blot, classified in class 435, subclass 6.

VI. Claim 15, drawn to a method for detecting polynucleotide encoding RCNγ having SEQ ID NO: 1 via PCR, classified in class 435, subclass 6.

VII. Claim 18, drawn to a method of treatment by administering RCNγ having SEQ ID NO: 1, classified in class 514, subclass 2.

VIII. Claim 19, drawn to a method for screening for an agonist using RCNγ having SEQ ID NO: 1 , classified in class 435, subclass 7.1.

IX. Claim 20, drawn to agonist of RCNγ having SEQ ID NO: 1, classified in class 530, subclass 350.

X. Claim 21, drawn to a method of treatment by administering the agonist of RCNγ having SEQ ID NO: 1, classified in class 514, subclass 2.

XI. Claim 22, drawn to a method for screening for an antagonist using RCNγ having SEQ ID NO: 1 , classified in class 435, subclass 7.1.

XII. Claim 23, drawn to antagonist of RCNγ having SEQ ID NO: 1, classified in class 530, subclass 350.

XIII. Claim 24, drawn to a method of treatment by administering the antagonist of RCNγ having SEQ ID NO: 1, classified in class 514, subclass 2.

XIV. Claim 25, drawn to a method for screening for compounds that bind RCNγ having SEQ ID NO: 1, classified in class 435, subclass 7.1.

XV. Claim 26, drawn to a method for screening for compounds that modulate the activity of RCNγ having SEQ ID NO: 1, classified in class 435, subclass 7.1.

XVI. Claim 27, drawn to a method for screening for compounds that alters the expression of nucleic acid encoding RCNγ having SEQ ID NO: 1 , classified in class 435, subclass 6.

XVII. Claim 28, drawn to a method for assessing the toxicity of a compound via nucleic acid encoding RCNγ having SEQ ID NO: 1 , classified in class 435, subclass 6.

XVIII. Claim 29, drawn to a diagnostic test via antibody against RCNγ having SEQ ID NO: 1 , classified in class 435, subclass 7.1.

XIX. Claim 32 and 34, drawn to a method of diagnosing via administration of the antibody against RCNγ having SEQ ID NO: 1 , classified in class 424, subclass 130.1.

XX. Claim 35 and 38, drawn to methods of making antibodies against RCNγ having SEQ ID NO: 1 , classified in class 424, subclass 130.1.

XXI. Claim 43, drawn to a method of detecting RCNγ via the antibody against RCNγ having SEQ ID NO: 1 , classified in class 435, subclass 7.1.

XXII. Claim 44, drawn to a method of purifying RCNγ via the antibody against RCNγ having SEQ ID NO: 1 , classified in class 435, subclass 7.1.

The inventions drawn to RCNγ are distinct, each from the other because of the following reasons:

The nucleic acids of Invention II are related to the protein of Invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of Invention I are related to the antibodies of Invention IV by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct Inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right,

or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The nucleic acid of Invention II and the antibody of Invention IV are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these Inventions are distinct.

The nucleic acid of Invention II and the transgenic organism are related in that the nucleic acid is used to make the organism. However, the products, that is the nucleic acid and the organim is wholly different and are therefore patentably distinct. Further, the nucleic acid can be used in other methods of making products, such as in the recombinant production of protein.

The protein of Invention I, and the antibody of Invention IV, the agonist of Invention IX, and the antagonist of Invention XII are not used in the making of the transgenic organism and are wholly different prducts from the organism. Therefore, Inventions I, IV, IX, and XII are patentably distinct from Invention III.

The protein of Invention I and the agonist of Invention IX are related in that both products have similar activities. However, the structure of the products are different and therefore these Inventions are patentably distinct.

The protein of Invention I and the antagonist of Invention XII have differing structure and opposing function. Therefore, these products are patentably distinct.

The nucleic acid of Invention II, the antibody of Invention IV, and the agonist of Invention IX, and the antagonist of Invention XII differ in structure and function. Therefore, Inventions II, IV, IX, and XII are patentably distinct one from the other.

Inventions I and Inventions VII, VIII, XIV, ,XV, or XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions VII, VIII, XIV, XV, or XX.

Inventions II and Inventions V, VI, XVI, or XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions V, VI, XVI, or XVII.

Inventions IX or XII and Inventions X or XIII, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions X or XIII or in the method of Invention VIII.

Inventions IV and Inventions XVIII, XIX, XXI, or XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions XVIII, XIX, XXI, or XXII.

Inventions XX and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by either method set form in Invention XX, or the method can be used to make other antibodies.

The product of Inventions I and IV are not used in the method of Inventions V, VI, X, XI, XIII, XVI, and XVII. Therefore, Inventions I and IV are patentably distinct from Inventions V, VI, X, XI, XIII, XVI, and XVII.

The product of Inventions I and II are not used in the methods of Inventions X, XIII, XVIII, XIX, XXI, or XII. Therefore, Inventions I and II are patentably distinct from Inventions X, XIII, XVIII, XIX, XXI, or XII.

The product of Inventions II and IV are not used in the methods of Inventions VII, VIII, X, XI, XIII, XIV, XV or XX. Therefore, Inventions II and V are patentably distinct from Inventions VII, VIII, X, XI, XIII, XIV, XV or XX.

The organism of Invention III is not used in any of the methods of Inventions V, VI, VII, VIII, X, XI, XIII-XXII. Therefore Invention III is patentably distinct from Inventions V, VI, VII, VIII, X, XI, XIII-XXII.

The product of Inventions IX or XIII is not used in the methods of Invention V-VIII, XI, XIV-XXI. Therefore, Inventions IX and XIII are patentably distinct from Inventions V-VIII, XI, XIV-XXI.

The methods of Inventions V-VIII, X, XI, XIII-XXII require different products and/or steps and have different endpoints. Therefore, Inventions V-VIII, X, XI, XIII-XXII are patentably distinct.

Because these inventions related to RCNγ are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

**RCNδ**

I. Claims 1, 2, 16, 17, and 45, drawn to RCNδ having SEQ ID NO: 3, classified in class 530, subclass 350.

II. Claims 3, 4, 5, 6, 7, 9, 11, and 12, drawn to polynucleotide encoding RCNδ having SEQ ID NO: 3, classified in class 536, subclass 23.1.

III. Claim 8, drawn to transgenic organism comprising polynucleotide encoding RCNδ having SEQ ID NO: 3, classified in class 800, subclass 8.

IV. Claims 10, 30, 31, 33, 36, 37, 39-42, drawn to antibody against RCNδ having SEQ ID NO: 3, classified in class 530, subclass 387.1.

V. Claims 13 and 14, drawn to a method for detecting polynucleotide encoding RCNδ having SEQ ID NO: 3 via Southern blot, classified in class 435, subclass 6.

VI. Claim 15, drawn to a method for detecting polynucleotide encoding RCNδ having SEQ ID NO: 3 via PCR, classified in class 435, subclass 6.

VII. Claim 18, drawn to a method of treatment by administering RCNδ having SEQ ID NO: 3, classified in class 514, subclass 2.

VIII. Claim 19, drawn to a method for screening for an agonist using RCNδ having SEQ ID NO: 3, classified in class 435, subclass 7.1.

IX. Claim 20, drawn to agonist of RCNδ having SEQ ID NO: 3, classified in class 530, subclass 350.

X. Claim 21, drawn to a method of treatment by administering the agonist of RCNδ having SEQ ID NO: 3, classified in class 514, subclass 2.

XI. Claim 22, drawn to a method for screening for an antagonist using RCNδ having SEQ ID NO: 3, classified in class 435, subclass 7.1.

XII. Claim 23, drawn to antagonist of RCNδ having SEQ ID NO: 3, classified in class 530, subclass 350.

XIII. Claim 24, drawn to a method of treatment by administering the antagonist of RCNδ having SEQ ID NO: 3, classified in class 514, subclass 2.

XIV. Claim 25, drawn to a method for screening for compounds that bind RCNδ having SEQ ID NO: 3, classified in class 435, subclass 7.1.

XV. Claim 26, drawn to a method for screening for compounds that modulate the activity of RCNδ having SEQ ID NO: 3, classified in class 435, subclass 7.1.

XVI. Claim 27, drawn to a method for screening for compounds that alters the expression of nucleic acid encoding RCNδ having SEQ ID NO: 3, classified in class 435, subclass 6.

XVII. Claim 28, drawn to a method for assessing the toxicity of a compound via nucleic acid encoding RCNδ having SEQ ID NO: 3, classified in class 435, subclass 6.

XVIII. Claim 29, drawn to a diagnostic test via antibody against RCNδ having SEQ ID NO: 3, classified in class 435, subclass 7.1.

XIX. Claim 32 and 34, drawn to a method of diagnosing via administration of the antibody against RCNδ having SEQ ID NO: 3 , classified in class 424, subclass 130.1.

XX. Claim 35 and 38, drawn to methods of making antibodies against RCNδ having SEQ ID NO: 3, classified in class 424, subclass 130.1.

XXI. Claim 43, drawn to a method of detecting RCNδ via the antibody against RCNδ having SEQ ID NO: 3, classified in class 435, subclass 7.1.

XXII. Claim 44, drawn to a method of purifying RCNδ via the antibody against RCNδ having SEQ ID NO: 3, classified in class 435, subclass 7.1.

The inventions drawn to RCNδ are distinct, each from the other because of the following reasons:

The nucleic acids of Invention II are related to the protein of Invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of Invention I are related to the antibodies of Invention IV by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct Inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The nucleic acid of Invention II and the antibody of Invention IV are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these Inventions are distinct.

The nucleic acid of Invention II and the transgenic organism are related in that the nucleic acid is used to make the organism. However, the products, that is the nucleic acid and the organim is wholly different and are therefore patentably distinct. Further, the nucleic acid can be used in other methods of making products, such as in the recombinant production of protein.

The protein of Invention I, and the antibody of Invention IV, the agonist of Invention IX, and the antagonist of Invention XII are not used in the making of the transgenic organism and are wholly different prducts from the organism. Therefore, Inventions I, IV, IX, and XII are patentably distinct from Invention III.

The protein of Invention I and the agonist of Invention IX are related in that both products have similar activities. However, the structure of the products are different and therefore these Inventions are patentably distinct.

The protein of Invention I and the antagonist of Invention XII have differing structure and opposing function. Therefore, these products are patentably distinct.

The nucleic acid of Invention II, the antibody of Invention IV, and the agonist of Invention IX, and the antagonist of Invention XII differ in structure and function. Therefore, Inventions II, IV, IX, and XII are patentably distinct one from the other.

Inventions I and Inventions VII, VIII, XIV, ,XV, or XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions VII, VIII, XIV, XV, or XX.

Inventions II and Inventions V, VI, XVI, or XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions V, VI, XVI, or XVII.

Inventions IX or XII and Inventions X or XIII, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions X or XIII or in the method of Invention VIII.

Inventions IV and Inventions XVIII, XIX, XXI, or XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions XVIII, XIX, XXI, or XXII.

Inventions XX and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by either method set form in Invention XX, or the method can be used to make other antibodies.

The product of Inventions I and IV are not used in the method of Inventions V, VI, X, XI, XIII, XVI, and XVII. Therefore, Inventions I and IV are patentably distinct from Inventions V, VI, X, XI, XIII, XVI, and XVII.

The product of Inventions I and II are not used in the methods of Inventions X, XIII, XVIII, XIX, XXI, or XII. Therefore, Inventions I and II are patentably distinct from Inventions X, XIII, XVIII, XIX, XXI, or XII.

The product of Inventions II and IV are not used in the methods of Inventions VII, VIII, X, XI, XIII, XIV, XV or XX. Therefore, Inventions II and V are patentably distinct from Inventions VII, VIII, X, XI, XIII, XIV, XV or XX.

The organism of Invention III is not used in any of the methods of Inventions V, VI, VII, VIII, X, XI, XIII-XXII. Therefore Invention III is patentably distinct from Inventions V, VI, VII, VIII, X, XI, XIII-XXII.

The product of Inventions IX or XIII is not used in the methods of Invention V-VIII, XI, XIV-XXI. Therefore, Inventions IX and XIII are patentably distinct from Inventions V-VIII, XI, XIV-XXI.

The methods of Inventions V-VIII, X, XI, XIII-XXII require different products and/or steps and have different endpoints. Therefore, Inventions V-VIII, X, XI, XIII-XXII are patentably distinct.

Because these inventions related to RCNδ are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

***

October 3, 2002